

REMARKS

Applicant traverses the rejection of the claims 1, 4, 6 and 7 under 35 USC 102(b) as anticipated by Krueger et al. Patent Number 5,868,253; claim 22 under 35 USC 102(b) as anticipated by Bowman et al. Patent Number 4,736,850 and claims 1-4, 6, 7, 14, and 15 under 35 USC 103(a) in view of Bowman et al. '850 when combined with Krueger et al. '253. Claims 16-18 and 25-32 were allowed and claims 5, 8-13, 20, 21, 23 and 24 were objected to but were indicated as being allowable if re-written in independent form. New claims 33-37 represent claims 5, 9, 12, 20 and 23 respectively written in independent form which have been indicated by the Examiner as allowable.

The Examiner's redundancy rejection on claim 5 is not understood. The outer container is impermeable and the inner container cover is permeable. There are two separate covers of two different compositions.

The specification has been amended to correct a typographical error. No new matter has been added.

The Bowman et al. '850 patent is directed to a cell harvesting kit comprising three trays contained in a packaging container 11. The first tray is an outer tray 12 with a lid 13. The lid 13 is sealed to a flange formed by the tray 12 and abuts against the inner surface of the side walls of the packaging container 11. A second component tray 14 is sized to fit in the cavity formed by the outer tray and is provided with a lid. A third process tray 31 is seated on the base of the component tray and is secured to the base. The process tray defines a trough 30 located within the center of the process tray. This trough holds the vein which is removed from the patient and cannula are placed in each end of the vein. The cannula are then placed in slots 32 located at each end of the trough 30. The process tray is fixed to the bottom of the component tray to preclude movement and has no

means of easy removal as claimed in the present invention. This fixed position is necessary as the vein must be rinsed, cut and filled with Diapase. Furthermore, Bowman et al. '850 does not disclose a stepped channel to hold tissue implants as the grooves 32 are cut through the end walls to hold the cannula fixed to the vein. (Figures 2 and 3). Bowman et al. '850 is not meant to hold an allograft tissue form in storage as it would fall out of the trough 30 during movement of the container and be almost impossible to place back in the trough once it was dislodged. The trough 30 simply acts as a seat for treatment of a vein taken from the patient being operated upon. This is an autologous procedure and not an allograft procedure.

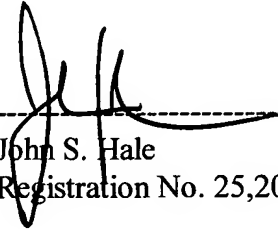
The Krueger et al. '253 patent discloses a mechanical heart valve package with an outer container, an inner heart valve container seated in the outer container and a two piece complex hinged retainer member mounted in the inner container to keep the heart valve in place. The hinged container member is mounted into the inner heart valve container through the use of a complex structure on the inner container. The '253 patent requires complex orientation of the component parts to arrive at a locking position.

None of the references teach an inclined end wall allowing easier stacking and storing of tissue transplant forms during treatment or the various defined shaped tissue form structures for retaining tissue within the inner container for later surgical use or a single piece removable insert for holding the allograft tissue in a predetermined position.

Applicant submits that the cited references do not teach, anticipate, or obviate the present invention either singularly or in combination and requests that the application be favorably reexamined and passed to issue. A check for the additional claims is attached to this Amendment together with a fee transmittal sheet.

Respectfully submitted,

GIPPLE & HALE



John S. Hale
Registration No. 25,209

6665-A Old Dominion Drive
McLean, Virginia 22101
(703) 448-1770 ext. 304
Attorney Reference: X-9353

LISTING OF SPECIFICATION WITH
MARKINGS TO SHOW CHANGES MADE

DETAILED DESCRIPTION OF THE INVENTION


B' The preferred embodiment and best mode of the tissue form package invention is shown in Figures 1, 2 and 4- 9. In the preferred embodiment of the present invention thin, plastic material is used that is sterilizable and that can be formed by any suitable method such as for example, injection molding, pressure molding, vacuum forming and the like. The component material used for the outer container 20 of the allograft bone tissue package assembly 10 is preferably made in the form of a laminate made of an available material such as ~~[polyethylene]~~ polyethylene terephthalateglycol (PETG) (a copolyester made by Eastman Chemical) as the inside layer, with the outside layer being another available material polychlorotrifluoroethylene (PCTFE) under the trademark ACLAR (a fluorinated-chlorinated thermoplastic made by Allied Corporation) which is impermeable to oxygen and other atmospheric gases and which is a highly moisture resistant barrier. Other suitable plastics which can be used for the outer container which work under the low temperature treatment conditions are low-density polyethylene, high-density polyethylene, cross-linked, high-density polyethylene, polycarbonate, polysulfone, fluorinated ethylene polypropylene, ethylene-tetrafluoroethylene, ethylene-chlorotrifluoroethylene copolymer, perfluoroalkoyl, polyurethane.

LISTING OF CLAIMS AND VERSION OF
CLAIMS WITH MARKINGS TO SHOW CHANGES MADE

Claim 1. (Currently Amended) A container assembly for storing sterile allograft tissue implant forms in a sterile condition comprising:

an outer container defining an open faced cavity and a flange extending outward from said cavity, a stepped recess formed in said flange surrounding said cavity;

an inner container defining a base, walls integrally formed with said base, said walls defining an open faced cavity and a flange extending outward from said cavity, said inner container flange being of a dimension to fit into said stepped recess of said outer container,

 ~~[an]~~ a one piece insert member sized to fit into said inner container cavity and removable from said inner container cavity, said insert member defining a linear shaped structure therein to hold a tissue implant form adjacent said inner container base;

a permeable cover sealed to the flange of the inner container covering said inner container cavity; and

an outer cover sealed to the flange of the outer container covering said outer container cavity.

Claim 2. (Original) A container assembly as claimed in Claim 1 wherein insert member comprises a housing defining notched recesses on opposing ends and a groove positioned between said notched recesses.

Claim 3. (Previously Amended) A container assembly as claimed in Claim 2 wherein said insert member has a housing which includes a lift tab extending from a side wall of said housing.

Claim 4. (Original) A container assembly as claimed in Claim 1 wherein said inner container cover includes a tab for grasping to remove the inner cover from the flange of said inner container.

Claim 5. (Canceled) A container assembly as claimed in Claim 1 wherein said outer container cover is impermeable.

Claim 6. (Original) A container assembly as claimed in Claim 1 wherein insert member shaped structure is a groove.

Claim 7. (Original) A container assembly as claimed in Claim 1 wherein said insert member shaped structure is a semicircular groove with stepped end portions which act as a retainer to seat a cylindrical shaped tissue implant form.

Claim 8. (Original) A container assembly as claimed in Claim 7 wherein insert member housing defines recesses formed in end walls of said housing which intersect a groove positioned transverse said semicircular groove with stepped end portions.

Claim 9. (Canceled) A container assembly as claimed in Claim 1 wherein said insert member shaped structure is a groove with angled side walls.

Claim 10. (Currently Amended) A container assembly as claimed in Claim ~~[9]~~ 34 wherein said angled side walls are of different widths.

Claim 11. (Previously Amended) A container assembly as claimed in Claim 6 wherein said insert member defines at least one recess which intersects said groove.

Claim 12. (Canceled) A container assembly as claimed in Claim 1 wherein both flanges of said outer container and said inner container have one end which extends outward further than the other portions of said flange to form a handle for the respective container.

Claim 13. (Currently Amended) A container assembly as claimed in Claim ~~[12]~~ 35 wherein at least one of said flanges forming a handle has a grasping rib formed thereon.

Claim 14. (Original) A container assembly as claimed in Claim 1 wherein said inner container has a housing defining an open faced cavity and a flange extending outward from said cavity, said

housing comprising a front end wall, side walls connected to said front end wall and an angularly oriented planar rear end wall, all of said walls being integrally connected with a base to form an interior cavity adapted to hold an insert member.

Claim 15. (Currently Amended) A package for storing sterile allograft tissue implant forms comprising:

an outer container defining an open faced cavity and a flange extending outward from said cavity, a stepped recess formed in said flange surrounding said cavity;

an inner container defining an open faced cavity and a flange extending outward from said cavity, said inner container flange being of a dimension to fit into said stepped recess of said outer container,

~~an~~ a removable one piece insert member sized to fit into said inner container cavity, said insert member defining a shaped depression formed therein to ~~hold~~ retain a tissue implant form within a chamber formed by said inner container and said shaped depression in a predetermined orientation;

a permeable cover sealed to the flange of the inner container covering said inner container cavity; and

an outer cover sealed to the flange of the outer container covering said outer container cavity.

Claim 16. (Original) A package for storing sterile allograft tissue implant forms comprising:

an outer container defining an open faced cavity and a flange extending outward from said cavity, a stepped recess formed in said flange surrounding said cavity;

an inner container defining an open faced cavity and a flange extending outward from said cavity, said inner container flange being of a dimension to fit into said stepped recess of said outer

container,

an insert member sized to fit into said inner container cavity, said insert member defining a groove therein to hold a tissue implant form and a second groove intersecting said first groove with a plurality of planar surfaces formed on the tissue implant form side of said insert member;

a permeable cover sealed to the flange of the inner container covering said inner container cavity; and

an outer cover sealed to the flange of the outer container covering said outer container cavity.

Claim 17. (Original) A container as claimed in claim 16 wherein said package container has a body with a rectangular configuration with planar end walls.

Claim 18. (Currently Amended) A container as claimed in claim 16 wherein said outer container has a laminated body with an inner layer of ~~[polyethylene]~~ polyethylene terephthalateglycol and an outer layer of ACKLAR.

Claim 19. (Currently Amended) A container for storing sterile allograft bone tissue forms comprising: a blister container housing defining an open faced cavity and a flange extending around said cavity outward from said cavity, said housing comprising a first end wall, side walls connected to said first end wall and an angularly oriented planar second end wall section angled toward said first end wall which forms a seat for said blister container housing, all of said walls being integrally connected with a base to form an interior cavity adapted to hold an insert member,

an insert member sized to fit into said container cavity, said insert member comprising a one piece housing defining a linear channel formed therein to hold a tissue implant form ~~[and having]~~, said insert member being provided with a tab member extending from one of it's walls; and

a permeable cover sealed to the flange of ~~[the inner]~~ said blister container covering said

container cavity.

Claim 20. (Canceled) A container as claimed in Claim 19 wherein said linear channel is formed by two angularly intersecting walls, one of said walls having a greater width than the other wall.

Claim 21. (Currently Amended) A container as claimed in Claim ~~[20]~~ 36 wherein said angularly oriented end walls are angled between 30 degrees and about 45 degrees.

2
b Claim 22. (Currently Amended) A container for storing sterile tissue forms comprising: a blister container housing defining an open faced cavity and a flange extending outward from said cavity, said housing comprising a front end wall, side walls connected to said front end wall and a rear end wall, all of said walls being integrally connected with a base to form an interior cavity adapted to hold ~~[an]~~ a removable insert member,

said insert member being sized to fit into said container cavity, said insert member comprising a housing defining a stepped arcuate groove to hold a tissue implant form in a predetermined position adjacent said container housing base and ~~[having]~~ being provided with a tab member extending from a housing wall; and

a removable cover sealed to the flange of the inner container covering said container cavity.

Claim 23. (Canceled) A container as claimed in Claim 22 wherein said housing defines at least one inclined channel intersecting said stepped arcuate groove.

Claim 24. (Currently Amended) A container as claimed in Claim ~~[23]~~ 37 wherein said housing further defines recesses in each end wall which lead into said at least one inclined channel.

Claim 25. (Previously Amended) A double sterile package container for storing sterile allograft tissue implant forms comprising:

an outer container defining an open faced cavity and a flange extending outward from said cavity, a stepped recess formed in said flange surrounding said cavity;

an inner container defining an open faced cavity and a flange extending outward from said cavity, said inner container flange being of a dimension to fit into said stepped recess of said outer container;

an insert member sized to fit into said inner container cavity, said insert member defining a linear depression therein to hold a tissue implant form;

a permeable cover sealed to the flange of the inner container covering said inner container cavity; and

an impermeable outer cover sealed to the flange of the outer container covering said outer container cavity.

Claim 26. (Original) A double sterile package container as claimed in Claim 25 wherein said insert member linear depression is a stepped arcuate groove adapted to hold a shaped implant form.

Claim 27. (Original) A double sterile package container as claimed in Claim 26 wherein said insert member housing defines a second arcuate groove which intersects said first stepped groove.

Claim 28. (Original) A double sterile package container as claimed in claim 25 wherein said insert member linear depression is a trough shaped depression.

Claim 29. (Original) A double sterile package container as claimed in claim 28 wherein said trough shaped depression is substantially V shaped.

Claim 30. (Original) A double sterile package container as claimed in claim 28 wherein said trough shaped depression is formed by intersecting angularly oriented side walls of different widths.

Claim 31. (Original) A sterile package for storing sterile allograft tissue implant forms

comprising:

an insert container comprising a housing with integral walls and a base defining an open faced cavity and a flange extending outward from said cavity, said housing being provided with at least one planar wall section which is angular to a plane of said base which can serve as a seat for said insert container;

an insert member sized to fit into said insert container cavity, said insert member comprising a housing defining a linear depression therein to hold a tissue implant form, said linear depression being formed by intersecting angular walls of said housing; and

a removable permeable cover sealed to said flange of the insert container covering said insert container cavity.

Claim 32. (Original) A sterile package for storing sterile allograft tissue implant forms comprising:

an insert container defining an open faced cavity and a flange extending outward from said cavity,

an insert member sized to fit into said inner container cavity, said insert member comprising a housing defining a curved groove with stepped ends forming shoulders to hold a tissue implant form, and at least one other groove intersecting at least a portion of said curved groove.; and

a removable cover sealed to the flange of the insert container covering said insert container cavity.

ADD THE FOLLOWING NEW CLAIMS:

Claim 33. (New) A container assembly for storing sterile allograft tissue implant forms in a sterile condition comprising:

an outer container defining an open faced cavity and a flange extending outward from said cavity, a stepped recess formed in said flange surrounding said cavity;

an inner container defining an open faced cavity and a flange extending outward from said cavity, said inner container flange being of a dimension to fit into said stepped recess of said outer container,

an insert member sized to fit into said inner container cavity, said insert member defining a shaped structure therein to hold a tissue implant form;

a permeable cover sealed to the flange of the inner container covering said inner container cavity; and

an outer impermeable cover sealed to the flange of the outer container covering said outer container cavity.

Claim 34. (New) A container assembly for storing sterile allograft tissue implant forms in a sterile condition comprising:

an outer container defining an open faced cavity and a flange extending outward from said cavity, a stepped recess formed in said flange surrounding said cavity;

an inner container defining an open faced cavity and a flange extending outward from said cavity, said inner container flange being of a dimension to fit into said stepped recess of said outer container,

an insert member sized to fit into said inner container cavity, said insert member defining a shaped structure in the form of a groove with angled side walls to hold a tissue implant form;

a permeable cover sealed to the flange of the inner container covering said inner container cavity; and

an outer cover sealed to the flange of the outer container covering said outer container cavity.

Claim 35. (New) A container assembly for storing sterile allograft tissue implant forms in a sterile condition comprising:

an outer container defining an open faced cavity and a flange extending outward from said cavity, a stepped recess formed in said flange surrounding said cavity;

an inner container defining an open faced cavity and a flange extending outward from said cavity, said inner container flange being of a dimension to fit into said stepped recess of said outer container,

an insert member sized to fit into said inner container cavity, said insert member defining a shaped structure therein to hold a tissue implant form;

a permeable cover sealed to the flange of the inner container covering said inner container cavity;

an outer cover sealed to the flange of the outer container covering said outer container cavity;
and

both flanges of said outer container and said inner container having one end which extends outward further than the other portions of said flange to form a handle for the respective container.

Claim 36. (New) A container for storing sterile tissue forms comprising:

a blister container housing defining an open faced cavity and a flange extending around said cavity outward from said cavity, said housing comprising a first end wall, side walls connected to said first end wall and an angularly oriented planar second end wall section which forms a seat for the blister container housing, all of said walls being integrally connected with a base to form an interior cavity adapted to hold an insert member,

an insert member sized to fit into said container cavity, said insert member comprising a housing defining a linear channel formed therein by two angularly intersecting walls with one of said walls having a greater width than the other wall to hold a tissue implant form and having a tab member extending from one of it's walls; and

a permeable cover sealed to the flange of the inner container covering said container cavity.

Claim 37. (New) A container for storing sterile tissue forms comprising:

b²
a blister container housing defining an open faced cavity and a flange extending outward from said cavity, said housing comprising a front end wall, side walls connected to said front end wall and a rear end wall, all of said walls being integrally connected with a base to form an interior cavity adapted to hold an insert member,

said insert member being sized to fit into said container cavity, said insert member comprising a housing defining a stepped arcuate groove to hold a tissue implant form and at least one inclined channel intersection said stepped arcuate groove and provided with a tab member extending from a housing wall; and

a removable cover sealed to the flange of the inner container covering said container cavity.
